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Supplemental Information Disclosure Statement

This Supplemental Information Disclosure Statement is submitted under 37 C.F.R. §1.97(c)(2) to supplement the Information Disclosure Statement filed on June 4, 2002 in connection with the subject application.

In accordance with their duty of disclosure under 37 C.F.R. \$1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (Exhibit A), and certain of which are attached hereto as Exhibits 1-132:

- U.S. Patent No. 5,464,933 issued November 7, 1995 to D.
 P. Bolognesi et al. (Exhibit 1);
- 2. U.S. Patent No. 5,603,933 issued February 18, 1997 to Dwyer, IV et al. (Exhibit 2);
- U.S. Patent No. 5,668,149 issued September 16, 1997 to S.
 Oroszlan et al. (Exhibit 3);
- 4. U.S. Patent No. 5,817,767 issued October 6, 1998 to G. P. Allaway et al. (Exhibit 4);
- U.S. Patent No. 5,994,515, issued November 30, 1999 to
 J.A. Hoxie (Exhibit 5);
- 6. U.S. Patent No. 6,528,625 B1, issued March 4, 2003 to L. Wu et al. (Exhibit 6);
- 7. U.S. Patent No. 6,548,636 B2, issued April 15, 2003 to T.

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Dragic and W.C. Olson (Exhibit 7);

- 8. U.S. Patent No. 6,692,745 B2, issued February 17, 2004 to W. C. Olson et al. (Exhibit 8);
- 9. U.S. Patent No. 6,759,519 issued July 6, 2004 to Y. Li and S. M. Ruben (Exhibit 9);
- 10. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/888,938, filed June 25, 2001 (Exhibit 10);
- 11. Allowed claims in T. Dragic and W.C. Olson, U.S. Serial No. 10/323,314, filed December 19, 2002 (Exhibit 11);
- 12. G.P. Allaway et al., U.S. Serial No. 08/627,684, filed April 2, 1996 (now abandoned) (Exhibit 12);
- 13. G.P. Allaway et al., U.S. Provisional Application No. 60/014,532, filed April 2, 1996;
- 14. G.P. Allaway et al., U.S. Serial No. 08/663,616, filed
 June 14, 1996 (now abandoned) (Exhibit 13);
- 15. G.P. Allaway et al., U.S. Provisional Application No. 60/019,715, filed June 14, 1996;
- 16. G.P. Allaway et al., U.S. Serial No. 08/673,682, filed
 June 25, 1996 (now abandoned) (Exhibit 14);
- 17. G.P. Allaway et al., U.S. Serial No. 08/665,090, filed
 June 14, 1996 (now abandoned) (Exhibit 15);

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- 18. G.P. Allaway et al., U.S. Provisional Application No. 60/019,941, filed June 14, 1996;
- 19. G.P. Allaway et al., U.S. Serial No. 08/874,570, filed
 June 13, 1997 (now abandoned) (Exhibit 16);
- 20. G.P. Allaway et al., U.S. Serial No. 08/874,618, filed
 June 13, 1997 (now abandoned) (Exhibit 17);
- 21. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/724,105, filed November 28, 2000 (Exhibit 18);
- 22. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/852,238 filed May 9, 2001 (Exhibit 19);
- 23. W.C. Olson and P.J. Maddon, U.S. Serial No. 09/212,793, filed December 16, 1998 (now abandoned);
- 24. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/112,532, filed December 16, 1998;
- 25. W.C. Olson and P.J. Maddon, U.S. Serial No. 09/464,902,
 filed December 16, 1999 (Exhibit 20);
- 26. W.C. Olson and P.J. Maddon, U.S. Serial No. 09/594,983, filed June 15, 2000 (Exhibit 21);
- 27. W.C. Olson et al., U.S. Serial No.09/663,219, filed
 September 15, 2000 (Exhibit 22);
- 28. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/282,380, filed April 6, 2001 (Exhibit 23);

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- 29. W.C. Olson et al., U.S. Provisional Application No. 60/266,738, filed February 6, 2001 (Exhibit 24);
- 30. W.C. Olson and P.J. Maddon, U.S. Patent Application Publication No. 2002/0146415 A1, published October 10, 2002 (Exhibit 25);
- 31. W.C. Olson and P.J. Maddon, U.S. Serial No. 10/081,128, filed February 22, 2002 (now abandoned) (Exhibit 26);
- 32. W.C. Olson and P.J. Maddon, U.S. Provisional Application No. 60/358,886, filed February 22, 2002;
- 33. William C. Olson and Paul J. Maddon, U.S. Publication No. 2003/0044411 A1, published March 6, 2003 (Exhibit 27);
- 34. T. Dragic and W.C. Olson, U.S. Patent Application Publication No. 2003/0092632 A1, published May 15, 2003 (Exhibit 28);
- 35. W.C. Olson et al., U.S. Patent Application Publication No. 2003/0228306 Al, published December 11, 2003 (Exhibit 29);
- 36. Pending claims in W.C. Olson and P.J. Maddon, U.S. Serial No. 10/763,545, filed January 23, 2004 (Exhibit 30);
- 37. Pending claims in G.P. Allaway et al., U.S. Serial No. 09/460,216, filed December 13, 1999 (Exhibit 31);
- 38. Y. Li et al. U.S. Patent Application Publication No. 2003/0023044, published January 30, 2003 (Exhibit 32);

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- 39. C. A. Rosen et al. U.S. Patent Application Publication No. 2002/0048786, published April 25, 2002 (Exhibit 33);
- 40. C. A. Rosen et al. U.S. Patent Application Publication No. 2002/0061834, published May 23, 2002 (Exhibit 34);
- 41. Y. Li et al. U.S. Patent Application Publication No. 2002/0076745, published June 20, 2002 (Exhibit 35);
- 42. Y. Li et al. U.S. Patent Application Publication No. US 2002/0099176, published July 25, 2002 (Exhibit 36);
- 43. M. Samson et al. U.S. Patent Application Publication No. 2002/0106742, published August 8, 2002 (Exhibit 37);
- 44. M. Samson et al. U.S. Patent Application Publication No. 2002/0110805, published August 15, 2002 (Exhibit 38);
- 45. M. Samson et al. U.S. Patent Application Publication No. 2002/0110870, published August 15, 2002 (Exhibit 39);
- 46. Y. Li et al. U.S. Patent Application Publication No. 2002/0132269, published September 19, 2002 (Exhibit 40);
- 47. Pending Claims in W.C. Olson and P.J. Maddon, U.S. Serial No. 10/681,879, filed October 9, 2003 (Exhibit 41);
- 48. PCT International Patent Application No. WO 92/01451 A1, published February 6, 1992 (Exhibit 42);
- 49. PCT International Application Publication No. WO 96/41020, published December 19, 1996 (Exhibit 43);

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- 50. PCT International Application Publication No. WO 97/26009, published July 24, 1997 (Exhibit 44);
- 51. PCT International Application Publication No. WO 97/37005, published October 27, 1997 (Exhibit 45);
- 52. PCT International Application Publication No. WO 97/45543, published December 4, 1997 (Exhibit 46);
- 53. PCT International Application Publication No. WO 97/47319, published December 18, 1997 (Exhibit 47);
- 54. PCT International Application Publication No. WO 97/49424, published December 31, 1997 (Exhibit 48);
- 55. PCT International Application Publication No. WO 98/18826, published May 7, 1998 (Exhibit 49);
- 56. PCT International Application Publication No. WO 98/56421, published December 17, 1998 (Exhibit 50);
- 57. PCT International Application Publication No. WO 00/35409, published June 22, 2000 (Exhibit 51);
- 58. PCT International Application Publication No. WO 01/55439, published August 2, 2001 (Exhibit 52);
- 59. PCT International Application Publication No. WO 01/64710, published September 7, 2001 (Exhibit 53);
- 60. PCT International Application Publication No. WO 02/22077, published March 21, 2002 (Exhibit 54);

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- 61. PCT International Application Publication No. WO 02/068608, published September 6, 2002 (Exhibit 55);
- 62. PCT International Application Publication No. WO 02/083172, published October 24, 2002 (Exhibit 56);
- 63. PCT International Application Publication No. WO 03/072766, published September 4, 2003 (Exhibit 57);
- 64. Allaway, G.P. et al. (1995) Expression and characterization of CD4-IgG2, a novel heterotetramer which neutralizes primary HIV-1 isolates. AIDS Res. Hum. Retroviruses 11: 533-539 (Exhibit 58);
- 65. Allaway, G.P. et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res. Hum. Retroviruses 9: 581-587 (Exhibit 59);
- 66. Allaway, G.P. et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. J. Cell. Biochem. 17E: 25, see abstract (Exhibit 60);
- 67. Amara, A. et al. (1997) HIV coreceptor downregulation as antiviral principle: SDF-la-dependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J. Exp. Med. 186: 139-146 (Exhibit 61);

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- 68. Arthos, J. et al. (1989) Identification of the residues in human CD4 critical for the binding of HIV. Cell 57: 469-481 (Exhibit 62);
- 69. Berger, E.A. 1997. HIV entry and tropism: the chemokine receptor connection. AIDS 11 (suppl A): S3-S16 (Exhibit 63);
- 70. Bieniasz, P.D. et al. (1997) HIV-1 induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR5 co-receptor. EMBO J. 16: 2599-2609 (Exhibit 64);
- 71. Brelot, A. et al. (1997) Role of the first and third extracellular domains of CXCR4 in human immunodeficiency virus coreceptor activity. J. Virol. 71: 4744-4751 (Exhibit 65);
- 72. Burkly, L. et al. (1995) Synergistic inhibition of human immunodeficiency virus type 1 envelope glycoprotein-mediated cell fusion and infection by an antibody to CD4 domain 2 in combination with anti-gp120 antibodies. J. Virol. 69: 4267-4273 (Exhibit 66);
- 73. Burton, D.R. et al. (1994) Efficient neutralization of primary isolates of HIV-1 by a recombinant human monoclonal antibody. Science 266: 1024-1027 (Exhibit 67);
- 74. Capon, D.J. et al. (1989) Designing CD4 immunoadhesins for AIDS therapy. Nature 337: 525-531 (Exhibit 68);

Serial No.: 09/912,824 Filed: July 25, 2001

- 75. Chan, D.C. et al. (1998) Evidence that a prominent cavity in the coiled coil of HIV type 1 gp41 is an attractive drug target. Proc. Natl. Acad. Sci. U.S.A. 95: 15613-15617 (Exhibit 69);
- 76. Chan, D.C. et al. (1998) HIV entry and its inhibition. Cell 93: 681-684 (Exhibit 70);
- 77. Chen, Z. et al. (1997) Genetically divergent strains of simian immunodeficiency virus use CCR5 as a coreceptor for entry. J. Virol. 71: 2705-2714 (Exhibit 71);
- 78. Choe, H. et al. (1996) The beta-chemokine receptors CCR3 and CCR5 facilitate infection by primary HIV-1 isolates.

 Cell 85: 1135-1148 (Exhibit 72);
- 79. Clapham, P.R. et al. (1989) Soluble CD4 blocks the infectivity of diverse strains of HIV and SIV for T cells and monocytes but not for brain and muscle cells. Nature 337: 368-370 (Exhibit 73);
- 80. Co, M.S. et al. (1991) Humanized antibodies for antiviral therapy. Proc. Natl. Acad. Sci. U.S.A. 88: 2869-2873 (Exhibit 74);
- 81. Connor, R.I. et al. (1997) Change in co-receptor use correlates with disease progression in HIV-1 infected individuals. J. Exp. Med. 185: 621-628 (Exhibit 75);
- 82. Crump, M.P. et al. (1997) Solution structure and basis for functional activity of stromal-cell derived factor-1;

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Page 23

disassociation of CXCR4 activation from binding and inhibition of HIV-1. EMBO J. 16: 6996-7007 (Exhibit 76);

- 83. Cushman, M. et al. (1991) Preparation and anti-HIV activities of aurintricarboxylic acid fractions and analogues: direct correlation of antiviral potency with molecular weight. J. Med. Chem. 34: 329-337 (Exhibit 77);
- 84. Dalgleish, A.G. et al. (1984) The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus. Nature 312: 763-766 (Exhibit 78);
- 85. Deen, K.C. et al. (1988) A soluble form of CD4 (T4) protein inhibits AIDS virus infection. Nature 331: 82-84 (Exhibit 79);
- 86. Deng, H. et al. (1996) Identification of a major coreceptor for primary isolates of HIV-1. Nature 381: 661-666 (Exhibit 80);
- 87. De Rossi, A. et al. (1995) Synthetic peptides from the principle neutralizing domain of human immunodeficiency virus type 1 (HIV-1) enhance HIV-1 infection through a CD4-dependent mechanism. Virology 184: 187-196 (Exhibit 81);
- 88. Donzella, G.A. et al. (1998) AMD3100, a small molecule inhibitor of HIV-1 entry via the CXCR4 co-receptor. Nat. Med. 4: 72-77 (Exhibit 82);
- 89. Doranz, B.J. et al. (1997) A small molecule inhibitor directed against the chemokine receptor CXCR4 prevents

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its use as an HIV-1 co-receptor. J. Exp. Med. 186: 1395-1400 (Exhibit 83);

- 90. Doranz, B.J. et al. (1996) A dual-tropic primary HIV-1 isolate that uses fusin and beta-chemokine receptors CKR-5, CKR-3, and CKR-2b as fusion cofactors. Cell 85: 1149-1158 (Exhibit 84);
- 91. Doranz, B.J. et al. (1997) Two distinct CCR5 domains can mediate co-receptor usage by human immunodeficiency virus type 1. J. Virol. 71: 6305-6314 (Exhibit 85);
- 92. Dragic, T. et al. (1996) HIV-1 entry into CD4+ cells is mediated by the chemokine receptor CC-CKR-5. Nature 381: 667-673 (Exhibit 86);
- 93. Eckert, D.M. et al. (1999) Inhibiting HIV-1 entry:
 Discovery of D-peptide inhibitors that target the gp41
 coiled-coil pocket. Cell 99: 103-115 (Exhibit 87);
- 94. Feng, Y. et al. (1996) HIV-1 entry cofactor: Functional cDNA cloning of a seven-transmembrane, G protein-coupled receptor. Science 272: 872-877 (Exhibit 88);
- 95. Ferrer, M. et al. (1999) Selection of gp41-mediated HIV-1 cell entry inhibitors from biased combinatorial libraries of non-natural binding elements. Nature Struct. Biol. 6: 953-959 (Exhibit 89);
- 96. Fouts, T.R. et al. (1997) Neutralization of the human immunodeficiency virus type 1 primary isolate JR-FL by human monoclonal antibodies correlates with antibody

Serial No.: 09/912,824 Filed: July 25, 2001

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binding to the oligomeric form of the envelope glycoprotein complex. J. Virol. 71: 2779-2785 (Exhibit 90);

- 97. Fradd, F. et al. (1989) AIDS Vaccines: An Investor's Guide by Shearman Lehaman Hutton. Page 10 (Fig. 2) (Exhibit 91);
- 98. Gait, M.J. et al. (1995) Progress in anti-HIV structure-based drug design. Trends Biotech. 13: 430-437 (Exhibit 92);
- 99. Gauduin, M.C. al. (1996) Effective et ex neutralization of plasma HIV-1 by recombinant immunoglobulin molecules. J. Virol. 70: 2586-2592 (Exhibit 93);
- 100. Hill, C.M. et al. (1998) The amino terminus of human CCR5 is required for its function as a receptor for diverse human and simian immunodeficiency virus envelope glycoproteins. Virology 248: 357-371 (Exhibit 94);
- 101. Jacobson, J. et al. (1999) Results of a phase I trial of single-dose PRO 542, a novel inhibitor of HIV entry.

 Abstracts of the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy 14 (Exhibit 95);
- 102. Ji, H. et al. (1999) Inhibition of human immunodeficiency virus type 1 infectivity by the gp41 core: role of a conserved hydrophobic cavity in membrane fusion. J. Virol. 73: 8578-8586 (Exhibit 96);

Serial No.: 09/912,824 Filed: July 25, 2001

- 103. Jiang, S. et al. (1993) HIV-1 inhibition by a peptide.

 Nature 365: 113 (Exhibit 97);
- 104. Kilby, J.M. et al. (1998) Potent suppression of HIV-1 replication in humans by T-20, a peptide inhibitor of gp41-mediated virus entry, Nature Med. 4: 1302-1307 (Exhibit 98);
- 105. Kwong, P.D. et al. (1998) Structure of an HIV gp120 envelope glycoprotein in complex with the CD4 receptor and a neutralizing human antibody. Nature 393: 648-659 (Exhibit 99);
- 106. Laal, S. et al. (1994) Synergistic neutralization of
 human immunodeficiency virus type 1 by combinations of
 human monoclonal antibodies. J. Virol. 68: 4001-4008
 (Exhibit 100);
- 107. LaCasse, R.A. et al. (1999) Fusion-competent vaccines: broad neutralization of primary isolates of HIV. Science 283: 357-362 (Exhibit 101);
- 108. Lehner, T. et al. (2001) Immunogenicity of the extracellular domains of C-C chemokine receptor 5 and the in vitro effects on simian immunodeficiency virus or HIV infectivity. J. Immunol. 166: 7446-7455 (Exhibit 102);
- 109. Li, A. et al. (1997) Synergistic neutralization of a chimeric SIV/HIV type 1 virus with combinations of human anti-HIV type 1 envelope monoclonal antibodies or hyperimmune globulins. AIDS Res. Hum. Retroviruses 13: 647-656 (Exhibit 103);

Serial No.: 09/912,824 Filed: July 25, 2001

- 110. Li, A. et al. (1998) Synergistic neutralization of simian-human immunodeficiency virus SHIV-vpu+ by triple and quadruple combinations of human monoclonal antibodies and high-titer anti-human immunodeficiency virus type 1 immunoglobulins. J. Virol. 72: 3235-3240 (Exhibit 104);
- 111. Litwin, V. et al. (1996) Human immunodeficiency virus type 1 membrane fusion mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer. J. Virol. 70: 6437-6441 (Exhibit 105);
- 112. Mack, M. et al. (1998) Aminooxypentane-RANTES induces CCR5 internalization but inhibits recycling: a novel inhibitory mechanisms of HIV infectivity. J. Med. 187: 1215-1224 (Exhibit 106);
- 113. Markosyan, R.M. et al. (2002) The mechanism of inhibition of HIV-1 Env-mediated cell-cell fusion by recombinant cores of gp41 ectodomain. Virology 302: 174-184 (Exhibit 107);
- 114. McKnight, A. et al. (1997) Inhibition of human immunodeficiency virus fusion by a monoclonal antibody to a co-receptor (CXCR3) is both cell type and virus strain dependent. J. Virol. 71: 1692-1696 (Exhibit 108);
- 115. Mohan, P. et al. (1992) Sulfonic acid polymers as a new class of human immunodeficiency virus inhibitors.

 Antiviral Res. 18: 139-150 (Exhibit 109);
- 116. Nagashima, K.A. et al. (2001) Human immunodeficiency virus type 1 entry inhibitors PRO 542 and T-20 are

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potently synergistic in blocking virus-cell and cell-cell fusion. J. Infect. Dis. 183: 1121-1125 (Exhibit 110);

- 117. Olson, W.C. et al. (1999) Differential inhibition of human immunodeficiency virus type 1 fusion, gp120 binding, and CC-chemokine activity by monoclonal antibodies to CCR5. J. Virol. 73: 4145-4155 (Exhibit 111);
- 118. Parren, P.W. et al. (2001) Antibody protects macaques against vaginal challenge with a pathogenic R5 simian/human immunodeficiency virus at serum levels giving complete neutralization in vitro. J. Virol. 75: 8340-8347 (Exhibit 112);
- 119. Posner, M.R. et al. (1993) Neutralization of HIV-1 by F105, a human monoclonal antibody to the CD4 binding site of gp120. J. Acq. Immune Defic. Synd. 6: 7-14 (Exhibit 113);
- 120. Rudikoff, et al. (1982) Single amino acid substitution altering antigen-binding specificity. Proc. Natl. Acad. Sci. U.S.A. 79: 1979-1983 (Exhibit 114);
- 121. Schols, D. et al. (1990) Dextran sulfate and other polyanionic anti-HIV compounds specifically interact with the viral gp120 glycoprotein expressed by T-cells persistently infected with HIV-1. Virology 175: 556-561 (Exhibit 115);
- 122. Schols, D. et al. (1991) Selective inhibitory activity of polyhydroxycarboxylates derived from phenolic compounds

Serial No.: 09/912,824 Filed: July 25, 2001

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against human immunodeficiency virus replication. J. Acq. Immune Defic. Synd. 4: 677-685 (Exhibit 116);

- 123. Strizki, J.M. et al. (1997) A monoclonal antibody (12G5) directed against CXCR4 inhibits infection with the dualtropic human immunodeficiency virus type 1 isolate HIV-1 89.6 but not the T-tropic isolate HIV-1 HxB J. Virol. 71: 5678-5683 (Exhibit 117);
- 124. Thali, M. et al. (1992) Cooperativity of neutralizing antibodies directed against the V3 and CD4 binding regions of the human immunodeficiency virus gp120 envelope glycoprotein. J. Acq. Immune Defic. Synd. 5: 591-599 (Exhibit 118);
- 125. Tilley, S.A. et al. (1992) Synergistic neutralization of HIV-1 by human monoclonal antibodies against the V3 loop and the CD4-binding site of gp120. AIDS Res. Hum. Retroviruses 8: 461-467 (Exhibit 119);
- 126. Tilley, S. A. et al. (1991) Potent neutralization of HIV-1 by human and chimpanzee monoclonal antibodies directed against three distinct epitope clusters of gp120. Sixieme Colloque Des Cent Gardes. pp. 211-216 (Exhibit 120);
- 127. Trkola, A. et al. (1996) CD4-dependent, antibody sensitive interactions between HIV-1 and its co-receptor CCR-5. Nature 384: 184-187 (Exhibit 121);
- 128. Trkola, A. et al. (2001) Potent, broad-spectrum inhibition of human immunodeficiency virus type 1 by the

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CCR5 monoclonal antibody PRO 140. J. Virol. 75: 579-588 (Exhibit 122);

- 129. Trkola, A. et al. (1998) Neutralization sensitivity of human immunodeficiency virus type 1 primary isolates to antibodies and CD4-based reagents is independent of coreceptor usage. J. Virol. 72: 1876-1885 (Exhibit 123);
- 130. Vijh-Warrier, S. et al. (1996) Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4- binding site. J. Virol. 70:4466-4473 (Exhibit 124);
- 131. Vita, C. et al. (1999) Rational engineering of a miniprotein that reproduces the core of the CD4 site interacting with HIV-1 envelope glycoprotein. Proc. Natl. Acad. Sci. U.S.A. 96: 13091-13096 (Exhibit 125);
- 132. Wild, C. et al. (1993) A synthetic peptide from HIV-1 gp41 is a potent inhibitor of virus- mediated cell-cell fusion. AIDS Res. Hum. Retroviruses 9: 1051-1053 (Exhibit 126);
- 133. Wild, C. et al. (1995) The inhibitory activity of an HIV type 1 peptide correlates with its ability to interact with a leucine zipper structure. AIDS Res. Hum. Retroviruses 11: 323-325 (Exhibit 127);
- 134. Wild, C. et al. (1992) A synthetic peptide inhibitor of human immunodeficiency virus replication: correlation

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between solution structure and viral inhibition. Proc. Natl. Acad. Sci. U.S.A. 89: 10537-10541 (Exhibit 128);

- 135. Wild, C. et al. (1994) Peptides corresponding to a predictive alpha-helical domain of human immunodeficiency virus type 1 gp41 are potent inhibitors of virus infection. Proc. Natl. Acad. Sci. U.S.A. 91: 9770-9774 (Exhibit 129);
- 136. Wu, L. et al. (1997) Interaction of chemokine receptor CCR5 with its ligands: multiple domains for HIV-1 gp120 binding and a single domain for chemokine binding. J. Exp. Med. 186: 1373-1381 (Exhibit 130);
- 137. Wu, L. et al. (1997) CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1, in vitro. J. Exp. Med. 185: 1681-1691 (Exhibit 131); and
- 138. Ylisastigui, L. et al. (1998) Synthetic full length and truncated RANTES inhibit HIV-1 infection of primary macrophages. AIDS 12: 977-984 (Exhibit 132).

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed PTO-1449 form.

C.F.R. \$1.98(a)(2)(iii) provides that an Information Disclosure Statement shall include, for each cited pending application, а legible сору οf the application specification including the claims and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion.

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Under 37 C.F.R. §1.98(c), when the disclosures of two or more patents or publications listed in an Information Disclosure Statement are substantively cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications, provided it is stated that these other patents or publications are cumulative. In accordance with 37 C.F.R. §1.98(c), copies of certain of the references listed above are not being submitted herewith as they are cumulative.

Specifically, U.S. Serial No. 09/888,938, filed June 25, 2001 (and published October 24, 2002 as U.S. Patent Application Publication No. 2002/0155429), is a continuation of U.S. Serial No. 10/831,823, filed April 2, 1997, which issued as U.S. Patent No. 6,344,545 B1. A copy of U.S. Patent No. 6,344,545 B1 was previously submitted to the Patent Office as Exhibit C in the Information Disclosure Statement filed in the subject application on June 4, 2002. Therefore, a copy of Publication No. 2002/0155429 Application is not However, in accordance with 37 \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 09/888,938 is attached hereto as Exhibit 10.

U.S. Serial No. 10/323,314, filed December 19, 2002 published July 24, 2003 as U.S. Patent Application Publication 2003/0139571), is a continuation of U.S. Serial No. 09/796,202, filed February 28, 2001 which issued as U.S. Patent No. 6,548,636 B2 (Exhibit 7). Therefore, a copy of Application Publication No. 2003/0139571 is not attached However, in accordance with 37 C.F.R. hereto. §1.98(a)(2)(iii), a copy of the claims allowed in U.S. Serial No. 10/323,314 is attached hereto as Exhibit 11.

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U.S. Serial No. 09/852,238, filed May 9, 2001 (and published 6, 2004 as U.S. Patent Application Publication No. 2004/0086528), is a continuation of 09/724,105, filed November 28, 2000, which is a continuation of U.S. Serial 08/874,618, filed June 13, 1997 (Exhibit 17). Therefore, copies 09/724,105 U.S. Serial No. and Application Publication 2004/0086528 attached hereto. No. are not However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), copies of the claims pending in U.S. Serial No. 09/724,105 and U.S. Serial No. 09/852,238 are attached hereto as Exhibits 18 and 19, respectively.

- U.S. Serial No. 10/763,545, filed January 23, 2004, is a continuation of U.S. Serial No. 09/594,983, filed June 15, 2000 (Exhibit 21). Therefore, a copy of U.S. Serial No. 10/763,545 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 10/763,545 is attached hereto as Exhibit 30.
- U.S. Serial No. 09/460,216, filed December 13, 1999, is a national stage application of PCT International Application Publication No. WO 98/56421, published December 17, 1998, (Exhibit 50). Therefore, a copy of U.S. Serial No. 09/460,216 is not attached hereto. However, in accordance with 37 C.F.R. \$1.98(a)(2)(iii), a copy of the claims pending in U.S. Serial No. 09/460,216 is attached hereto as Exhibit 31.

References 12 and 13 are cumulative to each other since each contains an identical disclosure. Therefore, a copy of reference 13 is not attached hereto.

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References 14 and 15 are cumulative to each other since each contains an identical disclosure. Therefore, a copy of reference 15 is not attached hereto.

References 17 and 18 are cumulative to each other since each contains an identical disclosure. Therefore, a copy of reference 18 is not attached hereto.

References 23, 24 and 25 are cumulative to each other since each contains an identical disclosure except that reference 20 contains an additional paragraph at the beginning of the application claiming the benefit of an earlier application, U.S. Provisional Application No. 60/112,532 (reference 24), and also provides the ATCC Accession Number for the PA10 antibody, which Accession Number is not provided in references 23 and 24. Therefore, copies of references 23 and 24 are not attached hereto.

References 31 and 32 are cumulative to each other since each contains an identical disclosure. Therefore, a copy of reference 32 is not attached hereto.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone them at the number provided below.

Pursuant to 37 C.F.R. §1.97(c)(2) and 1.17(p), a fee of one hundred and eighty dollars (\$180.00) is required for filing the enclosed Supplemental Information Disclosure Statement. A fee of four hundred and forty-three dollars (\$443.00) is also deemed necessary in connection with the filing of new claims

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and multiple dependent claims in this Amendment. Finally, a fee of four hundred and ninety dollars (\$490.00) is required for a three-month extension of time for responding to the April 20, 2004 Office Action. Accordingly, a check in the total amount of ONE THOUSAND AND ONE HUNDRED AND THIRTEEN DOLLARS (\$1,113.00) is enclosed. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

that correspondence is being deposited this date with the U.S. Postal

Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box

certify

1450, Alexandria, VA 22313-1450.

Alan J. Morrison Reg. No. 37, 399

hereby

Respectfully submitted,

John P. White Registration No. 28,678 Alan J. Morrison Registration No. 37,399 Attorney for Applicants Cooper & Dunham, LLP 1185 Avenue of the Americas New York, New York 10036

(212) 278-0400

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INFORMATION DISCLOSURE CITATION

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Atty. Docket No. Serial No. 62942-B/JPW/AJD 09/912,824

Applicant(s)

Graham P. Allaway et al.

Filing Date
July 25, 2001

Group Art Unit 1648

U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No. [§] | | Doc | ume | nt N | umb | er | | Date | Name | Class | Subclass | Filing Date If Appropriate |
|----------------------|--------------------------|---|-----|-----|------|-----|----|---|----------|------------------|-------|----------|----------------------------|
| | 1 | 5 | 4 | 6 | 4 | 9 | 6 | 3 | 11/07/95 | Bolognesi et al. | | | |
| | 2 | 5 | 6 | 0 | 3 | 9 | 3 | 3 | 02/18/97 | Dwyer et al. | | , | |
| | 3 | 5 | 6 | 6 | 8 | 1 | 4 | 9 | 09/16/97 | Oroszlan et al. | | | |
| | 4 | 5 | 8 | 1 | 7 | 7 | 6 | 7 | 10/06/98 | Allaway et al. | | | |

FOREIGN PATENT DOCUMENTS

| | | D | | - 4 BT | | | | Data | G | Class | G11 | Tran | slation |
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| 43 | 9 | 6 | 4 | 1 | 0 | 2 | 0 | 12/19/96 | PCT | | | | |
| 44 | 9 | 7 | 2 | 6 | 0 | 0 | 9 | 07/24/97 | PCT | | | | |
| 45 | 9 | 7 | 3 | 7 | 0 | 0 | 5 | 10/27/97 | PCT | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- Allaway, G.P. et al. (1995) Expression and characterization of CD4-IgG2, a novel heterotetramer which neutralizes primary HIV-1 isolates. AIDS Res. Hum. Retroviruses 11: 533-539;
 - Allaway, G.P. et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res. Hum. Retroviruses 9: 581-587;
 - 60 Allaway, G.P. et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. J. Cell. Biochem. 17E: 25, see abstract;

 61 Amara, A. et al. (1997) HIV coreceptor downregulation as antiviral principle: SDF-la-
 - Amara, A. et al. (1997) HIV coreceptor downregulation as antiviral principle: SDF-ladependent internalization of the chemokine receptor CXCR4 contributes to inhibition of HIV replication. J. Exp. Med. 186: 139-146;
 Arthos, J. et al. (1989) Identification of the residues in human CD4 critical for the
 - binding of HIV. Cell 57: 469-481;

 63 Berger, E.A. 1997. HIV entry and tropism: the chemokine receptor connection. AIDS 11
 - (suppl A): S3-S16;

 64 Bieniasz, P.D. et al. (1997) HIV-1 induced cell fusion is mediated by multiple regions within both the viral envelope and the CCR5 co-receptor. EMBO J. 16: 2599-2609;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Department of Commerce Patent and Trademark Office

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INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Filing Date Group Art Unit
July 25, 2001 1648

U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No.§ | | Doc | ume | nt N | umb | er | | Date | Name | Class | Subclass | Filing Date If Appropriate |
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| | 5 | 5 | 9 | 9 | 4 | 5 | 1 | 5 | 11/30/99 | Hoxie - | | | |
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| | 8 | 6 | 6 | 9 | 2 | 7 | 4 | 5 | 02/17/04 | Olson et al. | | | |
| | 9 | 6 | 7 | 5 | 9 | 5 | 1 | 9 | 07/06/04 | Li et al. | | | |
| | 10 | | | | cla 88,9 | | in | • | | Allaway et al. | | | 06/25/01 |

FOREIGN PATENT DOCUMENTS

| | | | | | | | | 5 | | | ~ | Tran | slation |
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| 48 | 9 | 7 | 4 | 9 | 4 | 2 | 4 | 12/31/97 | PCT | | | | |
| 49 | 9 | 8 | 1 | 8 | 8 | 2 | 6 | 05/07/98 | PCT | | | | |
| 50 | 9 | 8 | 5 | 6 | 4 | 2 | 1 | 12/17/98 | PCT | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| · | 65 | Brelot, A. et al. (1997) Role of the first and third extracellular domains of CXCR4 in |
|---|----|--|
| | | human immunodeficiency virus coreceptor activity. J. Virol. 71: 4744-4751; |
| | 66 | Burkly, L. et al. (1995) Synergistic inhibition of human immunodeficiency virus type 1 |
| | | envelope glycoprotein-mediated cell fusion and infection by an antibody to CD4 domain |
| | | 2 in combination with anti-gp120 antibodies. J. Virol. 69: 4267-4273; |
| | 67 | Burton, D.R. et al. (1994) Efficient neutralization of primary isolates of HIV-1 by a |
| : | | recombinant human monoclonal antibody. Science 266: 1024-1027; |
| | 68 | Capon, D.J. et al. (1989) Designing CD4 immunoadhesins for AIDS therapy. Nature |
| | | 337: 525-531; |
| | 69 | Chan, D.C. et al. (1998) Evidence that a prominent cavity in the coiled coil of HIV type |
| | | 1 gp41 is an attractive drug target. Proc. Natl. Acad. Sci. U.S.A. 95: 15613-15617; |

Chan, D.C. et al. (1998) HIV entry and its inhibition. Cell 93: 681-684;

EXAMINER

70

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

 Atty. Docket No.
 Serial No.

 62942-B/JPW/AJD
 09/912,824

Applicant(s)

Graham P. Allaway et al.

Filing Date
July 25, 2001

Group Art Unit 1648

U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No.§ | Document Number | | | | | | | Date | Name | Class | Subclass | Filing Date If Appropriate |
|----------------------|--------------|-----------------|---|------------|----|---|----|---|------|----------------|-------|----------|----------------------------|
| | 11 | 1 | | wec 0/3 | | | in | | | Dragic et al. | | | 12/19/02 |
| | 12 | 0.8 | 6 | 2 | 7 | 6 | 8 | 4 | | Allaway et al. | | | 04/02/96 |
| | | 60 | 0 | 1 | 4 | 5 | 3 | 2 | | Allaway et al. | | | 04/02/96 |
| | 13 | 08 | 6 | 6 | 3 | 6 | 1 | 6 | | Allaway et al. | | | 06/14/96 |
| | | 60 | 0 | 1 | 9 | 7 | 1 | 5 | | Allaway et al. | | | 06/14/96 |
| | 14 | 08 | 6 | 7 | 3 | 6 | 8 | 2 | | Allaway et al. | | | 06/25/96 |
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FOREIGN PATENT DOCUMENTS

| | | _ | | | | | | T | | | a. . | Tran | slation |
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| 54 | 0 | 2 | 2 | 2 | 0 | 7 | 7 | 03/21/02 | PCT | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

- 71 Chen, Z. et al. (1997) Genetically divergent strains of simian immunodeficiency virus use CCR5 as a coreceptor for entry. J. Virol. 71: 2705-2714;
 - 72 Choe, H. et al. (1996) The beta-chemokine receptors CCR3 and CCR5 facilitate infection by primary HIV-1 isolates. Cell 85: 1135-1148;
 - Clapham, P.R. et al. (1989) Soluble CD4 blocks the infectivity of diverse strains of HIV and SIV for T cells and monocytes but not for brain and muscle cells. Nature 337: 368-370;
 - Co, M.S. et al. (1991) Humanized antibodies for antiviral therapy. Proc. Natl. Acad. Sci. U.S.A. 88: 2869-2873;
 - Connor, R.I. et al. (1997) Change in co-receptor use correlates with disease progression in HIV-1 infected individuals. J. Exp. Med. 185: 621-628;
 Crump, M.P. et al. (1997) Solution structure and basis for functional activity of stromal-
 - Crump, M.P. et al. (1997) Solution structure and basis for functional activity of stromal-cell derived factor-1; disassociation of CXCR4 activation from binding and inhibition of HIV-1. EMBO J. 16: 6996-7007;

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Atty. Docket No. Serial No. 62942-B/JPW/AJD 09/912,824

Applicant(s)

Graham P. Allaway et al.

INFORMATION DISCLOSURE CITATION Filing Date July 25, 2001

Group Art Unit 1648

U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No.§ | | Doc | ume | nt N | umb | er | | Date | Name | Class | Subclass | Filing Date If Appropriate |
|----------------------|--------------|-----|-----|-----|-------------|-----|----|---|------|----------------|-------|----------|----------------------------|
| | | 60 | 0 | 1 | 9 | 9 | 4 | 1 | | Allaway et al. | | | 06/14/96 |
| | 16 | 0.8 | 8 | 7 | 4 | 5 | 7 | 0 | | Allaway et al. | | | 06/13/97 |
| | 17 | 0.8 | 8 | 7 | 4 | 6 | 1 | 8 | | Allaway et al. | | | 06/13/97 |
| | 18 |] | | | cla 24,1 | | in | | | Allaway et al. | | | 11/28/00 |
| | 19 |] | | | cla 52,2 | | in | | | Allaway et al. | | | 05/09/01 |
| | | 09 | 2 | 1 | 2 | 7 | 9 | 3 | | Olson et al. | | | 12/16/98 |
| | | 60 | 1 | 1 | 2 | 5 | 3 | 2 | | Olson et al. | | | 12/16/98 |

FOREIGN PATENT DOCUMENTS

| | | | | | | | | | | | | Tran | slation |
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| | | | | | | | | | | | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| 77 | Cushman, M. et al. (1991) Preparation and anti-HIV activities of aurintricarboxylic acid |
|--------|--|
| | fractions and analogues: direct correlation of antiviral potency with molecular weight. J. |
| | Med. Chem. 34: 329-337; |
| 78 | Dalgleish, A.G. et al. (1984) The CD4 (T4) antigen is an essential component of the |

receptor for the AIDS retrovirus. Nature 312: 763-766; 79 Deen, K.C. et al. (1988) A soluble form of CD4 (T4) protein inhibits AIDS virus

infection. Nature 331: 82-84; Deng, H. et al. (1996) Identification of a major co-receptor for primary isolates of HIV-1. 80 Nature 381: 661-666

De Rossi, A. et al. (1995) Synthetic peptides from the principle neutralizing domain of human immunodeficiency virus type 1 (HIV-1) enhance HIV-1 infection through a CD4dependent mechanism. Virology 184: 187-196

EXAMINER

81

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. Department of Commerce Patent and Trademark Office Atty. Docket No. Serial No. 62942-B/JPW/AJD 09/912,824
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U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No.§ | | Doc | ume | nt N | umb | er | | Date | Name | Class | Subclass | Filing Date If Appropriate | |
|----------------------|--------------|---|--|-----|-------------|------|-----|------|------------|------------------------------------|---------|-------------|----------------------------|--|
| | 20 | 09 | 4 | 6 | 4 | 9 | 0 | 2 | | Olson et al. | | | 12/16/99 | |
| | 21 | 09 | 5 | 9 | 4 | 9 | 8 | 3 | | Olson et al. | | | 06/15/00 | |
| | 22 | 09 | 6 | 6 | 3 | 2 | 1 | 9 | | Olson et al. | | | 09/15/00 | |
| | 23 | 60 | 2 | 8 | 2 | 3 | 8 | 0 | | Olson et al. | | | 04/06/01 | |
| | 24 | 60 | 2 | 6 | 6 | 7 | 3 | 8 | | Olson et al. | | - | 02/06/01 | |
| | 25 | 2 | 0 0 | 2/0 | 1 4 | 6 4 | 1 5 | 5 | 10/10/02 | Olson et al. | | | | |
| | 26 | 10 | 0 | 8 | 1 | 1 | 2 | 8 | | Olson et al. | | | 02/22/02 | |
| | OTI | IER I | DOC | CUN | ME I | NTS | (Ir | ıclu | ding Autho | or, Title, Date, P | ertiner | t Pages, E | tc.) | |
| | 82 | the (| Donzella, G.A. et al. (1998) AMD3100, a small molecule inhibitor of HIV-1 entry value CXCR4 co-receptor. Nat. Med. 4: 72-77; Doranz, B.L. et al. (1997) A small molecule inhibitor directed against the chemoki | | | | | | | | | | | |
| | 83 | Doranz, B.J. et al. (1997) A small molecule inhibitor directed against the chem receptor CXCR4 prevents its use as an HIV-1 co-receptor. J. Exp. Med. 186: 1395- | | | | | | | | | | | | |
| | 84 | | nok | | | | • | • | - | oic primary HIV- , and CKR-2b a | | | | |
| | 85 | | | | | | | | | t CCR5 domains . J. Virol. 71: 63 | | | ceptor usage by | |
| | 86 | Drag | gic, | Т. | et a | 1. (| 199 | 6) I | | into CD4+ cel | | | the chemokine | |
| | 87 | | | | | | | | | HIV-1 entry: Dise 199: 103-115; | covery | of D-peptid | e inhibitors that | |
| | 88 | Feng | target the gp41 coiled-coil pocket. Cell 99: 103-115; Feng, Y. et al. (1996) HIV-1 entry cofactor: Functional cDNA cloning of a seven-transmembrane, G protein-coupled receptor. Science 272: 872-877; | | | | | | | | | | | |
| | 89 | Ferrer, M. et al. (1999) Selection of gp41-mediated HIV-1 cell entry inhibitors from biased combinatorial libraries of non-natural binding elements. Nature Struct. Biol. 6: 953-959; | | | | | | | | | | | | |
| | 90 | | | | | | | | | ion of the huma oclonal antibodie | | | | |

EXAMINER

91

Hutton. Page 10 (Fig. 2);

DATE CONSIDERED

to the oligomeric form of the envelope glycoprotein complex. J. Virol. 71: 2779-2785; Fradd, F. et al. (1989) AIDS Vaccines: An Investor's Guide by Shearman Lehaman

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE CITATION

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Atty. Docket No. 62942-B/JPW/AJD 09/912,824
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Applicant(s)
Graham P. Allaway et al.

Filing Date
July 25, 2001

Group Art Unit 1648

U.S. PATENT DOCUMENTS

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| Examiner Initials | Exh. No.§ | Document Number | Date | · Name | Class | Subclass | Filing Date If Appropriate | | | | | | | |
| | | 60 3 5 8 8 8 6 | | Olson et al. | | | 02/22/02 | | | | | | | |
| , | 27 | 2003/0044411 | 03/06/03 | Olson et al. | | | | | | | | | | |
| | 28 | 2003/0092632 | 05/15/03 | Dragic et al. | | | | | | | | | | |
| | 29 | 2003/0228306 | 12/11/03 | Olson et al. | | | | | | | | | | |
| | 30 | Pending claims in 10/763,545 | | Olson et al. | | | 01/23/04 | | | | | | | |
| | 31 | Pending claims in 09/460,216 | | Allaway et al. | | | 12/13/99 | | | | | | | |
| | OTF | HER DOCUMENTS (Inclu | ding Autho | or, Title, Date, P | ertinen | t Pages, E | tc.) | | | | | | | |
| | 92 | Gait, M.J. et al. (1995) Biotech. 13: 430-437; | Progress i | n anti-HIV stru | cture-ba | ased drug | design. Trends | | | | | | | |
| | 93 | recombinant immunoglobulin molecules. J. Virol. 70: 2586-2592; | | | | | | | | | | | | |
| | 94 | Hill, C.M. et al. (1998) Thas a receptor for diverglycoproteins. Virology 24 | e amino te se human | rminus of human and simian in | CCR5 | is required | | | | | | | | |
| | 95 | Jacobson, J. et al. (1999) inhibitor of HIV entry. At Agents and Chemotherapy | Results of ostracts of | a phase I trial | | | | | | | | | | |
| | 96 | Ji, H. et al. (1999) Inhibition gp41 core: role of a cons 8578-8586; | on of huma | | | | | | | | | | | |
| | 97 | | | | | | | | | | | | | |
| | 98 | Kilby, J.M. et al. (1998) Potent suppression of HIV-1 replication in humans by T-20, peptide inhibitor of gp41-mediated virus entry, Nature Med. 4: 1302-1307; | | | | | | | | | | | | |
| | 99 | Kwong, P.D. et al. (1998) with the CD4 receptor and | Structure o | f an HIV gp120 | envelop | e glycopro | tein in complex | | | | | | | |
| - | 100 | Laal, S. et al. (1994) Syner | rgistic neut | ralization of hum | an imm | unodeficie | ncy virus type 1 | | | | | | | |
| | by combinations of human monoclonal antibodies. J. Virol. 68: 4001-4008; 101 LaCasse, R.A. et al. (1999) Fusion-competent vaccines: broad neutralization of primary isolates of HIV. Science 283: 357-362; | | | | | | | | | | | | | |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE CITATION

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Graham P. Allaway et al.

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U.S. PATENT DOCUMENTS

| Examiner Initials | Exh. No.§ | | Doci | umen | t N | umb | er | | Date | Name | Class | Subclass | Filing Date If Appropriate |
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| | 32 | 2 (| 0 0 3 | 3/0 | 0 2 | 23 (|) 4 4 | 4 | 01/30/03 | Li et al. | | , | |
| | 33 | 2 (| 0 0 2 | 2/0 | 0 4 | 187 | 78 | 6 | 04/25/02 | Rosen et al. | | | |
| | 34 | 2 (| 0 0 2 | 2/0 | 0 6 | 518 | 3 3 4 | 4 | 05/23/02 | Rosen et al. | | ٠ | |
| | 35 | 2 (| 0 0 2 | 2/0 | 0 7 | 767 | 7 4 : | 5 | 06/20/02 | Li et al. | | | |
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| | 37 | 2 (| 0 0 2 | 2/0 | 1 (| 67 | 742 | 2 | 08/08/02 | Samson et al. | | | |
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| | 39 | 2 (| 0 0 2 | 2/0 | 1 1 | 0.8 | 37(| 0 | 08/15/02 | Samson et al. | | | |
| | 40 | 2 (| 0 0 2 | 2/0 | 1 3 | 3 2 2 | 269 | 9 | 09/19/02 | Li et al. | | | |
| · | 41 | Pending claims in 10/681,879 | | | | | in | | | Olson et al. | | | 10/09/03 |
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| | 102 | rece | ptor | 5 aı | nd ' | the | in v | itro | effects on | ity of the extraction immunod | | | |
| | 103 | J. Immunol. 166: 7446-7455; Li, A. et al. (1997) Synergistic neutralization of a chimeric SIV/HIV type 1 virus with combinations of human anti-HIV type 1 envelope monoclonal antibodies or hyperimmune globulins. AIDS Res. Hum. Retroviruses 13: 647-656; Li, A. et al. (1998) Synergistic neutralization of simian-human immunodeficiency virus SHIV-vpu+ by triple and quadruple combinations of human monoclonal antibodies and high-titer anti-human immunodeficiency virus type 1 immunoglobulins. J. Virol. 72: 3235-3240; Litwin, V. et al. (1996) Human immunodeficiency virus type 1 membrane fusion mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer. J. Virol. 70: 6437-6441; | | | | | | | | | | | |
| | 104 | | | | | | | | | | | | |
| | 105 | | | | | | | | | | | | |
| | 106 | Mack, M. et al. (1998) Aminooxypentane-RANTES induces CCR5 internalization but inhibits recycling: a novel inhibitory mechanisms of HIV infectivity. J. Med. 187: 1215-1224; | | | | | | | | | | | |

EXAMINER

DATE CONSIDERED

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Atty. Docket No. Serial No. 62942-B/JPW/AJD 09/912,824 Applicant(s) Graham P. Allaway et al.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Filing Date Group Art Unit July 25, 2001 1648

| | July 23, 2001 1048 | | | | | | | |
|----------|---|--|--|--|--|--|--|--|
| ОТ | HER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | |
| 107 | Markosyan, R.M. et al. (2002) The mechanism of inhibition of HIV-1 Env-mediated cell- | | | | | | | |
| | cell fusion by recombinant cores of gp41 ectodomain. Virology 302: 174-184; | | | | | | | |
| 108 | McKnight, A. et al. (1997) Inhibition of human immunodeficiency virus fusion by a | | | | | | | |
| | monoclonal antibody to a co-receptor (CXCR3) is both cell type and virus strain | | | | | | | |
| | dependent. J. Virol. 71: 1692-1696; | | | | | | | |
| 109 | Mohan, P. et al. (1992) Sulfonic acid polymers as a new class of human | | | | | | | |
| '*' | immunodeficiency virus inhibitors. Antiviral Res. 18: 139-150; | | | | | | | |
| 110 | Nagashima, K.A. et al. (2001) Human immunodeficiency virus type 1 entry inhibitors | | | | | | | |
| | PRO 542 and T-20 are potently synergistic in blocking virus-cell and cell-cell fusion. J. | | | | | | | |
| · | Infect. Dis. 183: 1121-1125; | | | | | | | |
| 111 | Olson, W.C. et al. (1999) Differential inhibition of human immunodeficiency virus type | | | | | | | |
| ` | 1 fusion, gp120 binding, and CC-chemokine activity by monoclonal antibodies to CCR5. | | | | | | | |
| | J. Virol. 73: 4145-4155; | | | | | | | |
| 112 | Parren, P.W. et al. (2001) Antibody protects macaques against vaginal challenge with a | | | | | | | |
| . | pathogenic R5 simian/human immunodeficiency virus at serum levels giving complete | | | | | | | |
| | neutralization in vitro. J. Virol. 75: 8340-8347; | | | | | | | |
| 113 | Posner, M.R. et al. (1993) Neutralization of HIV-1 by F105, a human monoclonal | | | | | | | |
| | antibody to the CD4 binding site of gp120. J. Acq. Immune Defic. Synd. 6: 7-14; | | | | | | | |
| 114 | Rudikoff, et al. (1982) Single amino acid substitution altering antigen-binding | | | | | | | |
| | specificity. Proc. Natl. Acad. Sci. U.S.A. 79: 1979-1983; | | | | | | | |
| 115 | Schols, D. et al. (1990) Dextran sulfate and other polyanionic anti-HIV compounds | | | | | | | |
| | specifically interact with the viral gp120 glycoprotein expressed by T-cells persistently | | | | | | | |
| | infected with HIV-1. Virology 175: 556-561; | | | | | | | |
| 116 | Schols, D. et al. (1991) Selective inhibitory activity of polyhydroxycarboxylates derived | | | | | | | |
| | from phenolic compounds against human immunodeficiency virus replication. J. Acq. | | | | | | | |
| | Immune Defic. Synd. 4: 677-685; | | | | | | | |
| 117 | Strizki, J.M. et al. (1997) A monoclonal antibody (12G5) directed against CXCR4 | | | | | | | |
| | inhibits infection with the dual-tropic human immunodeficiency virus type 1 isolate | | | | | | | |
| | HIV-1 89.6 but not the T-tropic isolate HIV-1 HxB J. Virol. 71: 5678-5683; | | | | | | | |
| 118 | Thali, M. et al. (1992) Cooperativity of neutralizing antibodies directed against the V3 | | | | | | | |
| | and CD4 binding regions of the human immunodeficiency virus gp120 envelope | | | | | | | |
| | glycoprotein. J. Acq. Immune Defic. Synd. 5: 591-599; | | | | | | | |
| 119 | Tilley, S.A. et al. (1992) Synergistic neutralization of HIV-1 by human monoclonal | | | | | | | |
| | antibodies against the V3 loop and the CD4-binding site of gp120. AIDS Res. Hum. | | | | | | | |
| | Retroviruses 8: 461-467; | | | | | | | |
| 120 | Tilley, S. A. et al. (1991) Potent neutralization of HIV-1 by human and chimpanzee | | | | | | | |
| | monoclonal antibodies directed against three distinct epitope clusters of gp120. Sixieme | | | | | | | |
| | Colloque Des Cent Gardes. pp. 211-216 | | | | | | | |
| EXAMINER | DATE CONSIDERED | | | | | | | |

^{*}EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE CITATION

Atty. Docket No. Serial No. 62942-B/JPW/AJD 09/912,824

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| | (Use several sheets if necessary) | July 25, 2001 | 1648 | | | | |
|----------|--|-------------------------|-----------|--|--|--|--|
| OT | HER DOCUMENTS (Including Author, Title | e, Date, Pertinent Page | es, Etc.) | | | | |
| 121 | Trkola, A. et al. (1996) CD4-dependent, antibody sensitive interactions between HIV-1 and its co-receptor CCR-5. Nature 384: 184-187; | | | | | | |
| 122 | Trkola, A. et al. (2001) Potent, broad-spectrum inhibition of human immunodeficiency virus type 1 by the CCR5 monoclonal antibody PRO 140. J. Virol. 75: 579-588; | | | | | | |
| 123 | Trkola, A. et al. (1998) Neutralization sensitivity of human immunodeficiency virus type 1 primary isolates to antibodies and CD4-based reagents is independent of coreceptor usage. J. Virol. 72: 1876-1885; | | | | | | |
| 124 | Vijh-Warrier, S. et al. (1996) Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4- binding site. J. Virol. 70:4466-4473; | | | | | | |
| 125 | Vita, C. et al. (1999) Rational engineering of a miniprotein that reproduces the core of the CD4 site interacting with HIV-1 envelope glycoprotein. Proc. Natl. Acad. Sci. U.S.A. 96: 13091-13096; | | | | | | |
| 126 | Wild, C. et al. (1993) A synthetic peptide from HIV-1 gp41 is a potent inhibitor of virus-mediated cell-cell fusion. AIDS Res. Hum. Retroviruses 9: 1051-1053; | | | | | | |
| 127 | Wild, C. et al. (1995) The inhibitory activity of an HIV type 1 peptide correlates with its ability to interact with a leucine zipper structure. AIDS Res. Hum. Retroviruses 11: 323-325; | | | | | | |
| 128 | Wild, C. et al. (1992) A synthetic peptide inhibitor of human immunodeficiency virus replication: correlation between solution structure and viral inhibition. Proc. Natl. Acad. Sci. U.S.A. 89: 10537-10541; | | | | | | |
| 129 | Wild, C. et al. (1994) Peptides corresponding to a predictive alpha-helical domain of human immunodeficiency virus type 1 gp41 are potent inhibitors of virus infection. Proc. Natl. Acad. Sci. U.S.A. 91: 9770-9774; | | | | | | |
| 130 | Wu, L. et al. (1997) Interaction of chemokine receptor CCR5 with its ligands: multiple domains for HIV-1 gp120 binding and a single domain for chemokine binding. J. Exp. Med. 186: 1373-1381; | | | | | | |
| 131 | Wu, L. et al. (1997) CCR5 levels and expression pattern correlate with infectability by macrophage-tropic HIV-1, <i>in vitro</i> . J. Exp. Med. 185: 1681-1691; and | | | | | | |
| 132 | Ylisastigui, L. et al. (1998) Synthetic full length and truncated RANTES inhibit HIV-1 infection of primary macrophages. AIDS 12: 977-984. | | | | | | |
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| EXAMINER | DATE CONSI | DERED | | | | | |

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